



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

STW

APPLICANT: Nicolle Hannah Packer  
APPLICATION NO.: 10/528,745  
FILING DATE: March 22, 2005  
TITLE: Method of Identifying Markers Diagnostic of Disease and Uses  
Therefore in the Diagnosis of Cancer  
EXAMINER: Not Yet Known  
GROUP ART UNIT: Not Yet Known  
ATTY. DKT. NO.: 23681-10204US (Client Ref. 122502)

MAIL STOP AMENDMENT  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**Under 37 CFR §§ 1.56 and 1.97-98**

SIR:

Pursuant to the provisions of 37 CFR §§ 1.56 and 1.97-98, enclosed herewith is modified form PTO/SB/08A listing references for consideration by the Examiner.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:

- ☒ within three months of the filing date of the application, or date of entry into the national stage of an international application, or before the mailing date of a first office action on the merits, whichever event last occurred;
- ☐ before the mailing of a first official action after the filing of a request for continued examination (RCE) under 37 CFR § 1.114;
- ☐ after three months of the filing date of this national application or the date of entry of the national stage in an international application, or after the mailing date of the first official action on the merits, whichever event last occurred, but before the mailing date of the first to occur of either: (1) a final action under

37 CFR §1.113; or (2) an action that otherwise closes prosecution in the application, and:

- ☐ attached hereto is the fee set forth under 37 CFR §1.17(p) for submission of this Information Disclosure Statement under 37 CFR. § 1.97(c); OR
- ☐ Applicant certifies pursuant to 37 CFR § 1.97(e) that:
  - ☐ each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement; OR
  - ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 CFR § 1.56(c) more than three months prior to the filing of this Statement;
- ☐ on or before the payment of the issue fee but after the mailing date of the first to occur of either: (1) a final action under 37 CFR § 1.113; (2) a notice of allowance under 37 CFR § 1.311; or (3) an action that otherwise closes prosecution in the application, and:
  - ☐ Applicant certifies pursuant to 37 CFR. § 1.97(e) that:
    - ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement;
    - ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 CFR § 1.56(c) more than three months prior to the filing of this Statement; AND

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- ☐ attached hereto is the fee set forth under 37 CFR §1.17(p) for submission of this Information Disclosure Statement under 37 CFR. § 1.97(d); OR
- ☐ after the payment of the issue fee. Applicant requests that the information contained in this Information Disclosure Statement be placed in the file according to 37 CFR § 1.97(i), although the information may not be considered by the USPTO.
- ☒ Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose.
- ☐ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. \_\_\_\_\_, filed on \_\_\_\_\_, and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 CFR § 1.98(d).
- ☐ This application was filed after June 30, 2003. Therefore, pursuant to the waiver of the requirements under 37 CFR 1.98(a)(2)(i), copies of each U.S. Patent and each U.S. Patent Application Publication are not required to be submitted. Copies of any foreign patent documents and non-patent literature cited herein are enclosed.
- ☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 CFR § 1.56(c) more than thirty days prior to the filing of this Information Disclosure Statement. 37 CFR § 1.704(d).
- ☒ Applicant submits that no fee is required for the consideration of this Information Disclosure Statement.

Consideration of the listed references and favorable action are solicited.

Respectfully submitted,  
NICOLLE HANNAH PACKER

Dated: 8/9/06

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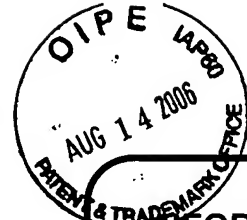
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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence during pendency of filed application)</i>		Application Number	10,528,745
		Filing Date	March 22, 2005
		First Named Inventor	Nicolle Hannah Packer
		Group Art Unit Number	Not Yet Known
		Examiner Name	Not Yet Known
Total Number of Pages in This Submission	6*	Attorney Docket Number	23681-10204/US

ENCLOSURES (check all that apply)	
<input type="checkbox"/> Fee Transmittal Form (in duplicate) <input type="checkbox"/> Check Enclosed <input checked="" type="checkbox"/> Return Receipt Postcard <input type="checkbox"/> Response to Notice to File Missing Parts <input type="checkbox"/> Assignment & Recordation Cover Sheet <input type="checkbox"/> Declaration <input type="checkbox"/> Power of Attorney <input type="checkbox"/> Application Data Sheet <input checked="" type="checkbox"/> Information Disclosure Statement & PTO/SB/08A <input checked="" type="checkbox"/> Copies of IDS Cited References (14) <input type="checkbox"/> Request for Corrected Filing Receipt <input type="checkbox"/> Request for Correction of Recorded Assignment <input type="checkbox"/> Amendment/Response: [ ] Page(s) <input type="checkbox"/> After Final <input type="checkbox"/> Status Request <input type="checkbox"/> Revocation and Substitute Power of Attorney	<input type="checkbox"/> Issue Fee Transmittal <input type="checkbox"/> Letter to Chief Draftsperson <input type="checkbox"/> Formal Drawing(s): [ ] Sheet(s) of Figure(s) [ ] <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
REMARKS: *Total Number of Pages in this Submission does not include cited references.	

SIGNATURE OF ATTORNEY OR AGENT			
Signature:			
Attorney/Reg. No.:	Susan T. Hubl, Ph.D., Reg. No. 47,668, Patent Agent	Dated:	8/7/06

CERTIFICATE OF MAILING			
I hereby certify that this correspondence, including the enclosures identified above, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. If the Express Mail Mailing Number is filled in below, then this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service pursuant to 37 CFR 1.10.			
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Typed or Printed Name:	Susan T. Hubl	Dated:	8/7/06
Express Mail Mailing Number (optional):			



Substitute for form 1449A/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

Submitted on 08/09/06

**Complete if Known**

Application No.	10/528,745
Filing Date	March 22, 2005
First Named Inventor	Nicolle Hannah Packer
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	23681-10204US (Client Ref 122502)

Sheet 1 of 2

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document No. Number – Kind Code <sup>2</sup> (if known)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,228,654	05-08-2001	Chait et al.

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> – Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
		WO 03/016464 A2	02-27-2003	Carbion OY	
		WO 02/08760 A1	01-31-2002	Biotron Limited	
		WO 01/36977 A2	05-25-2001	Matritech, Inc.	

## **OTHER REFERENCES – NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>6</sup>
		BELANGER, A. et al., "Molecular Mass and Carbohydrate Structure of Prostate Specific Antigen: Studies for Establishment of an International PSA Standard," The Prostate, 1995, pp. 187-197, Vol. 27.	
		CAPON, C. et al., "Oligosaccharide Structures of Mucins Secreted by the Human Colonic Cancer Cell Line CL. 16E," The Journal of Biological Chemistry, 1992, pp. 19248-19257, Vol. 267, No. 27.	
		DWEK, M.V. et al., "Oligosaccharide Release from Frozen and Paraffin-Wax-Embedded Archival Tissues," Analytical Biochemistry, 1996, pp. 8-14, Vol. 242.	
		FUKUDA, M. et al., "Structures of O-Linked Oligosaccharides Isolated from Normal Granulocytes, Chronic Myelogenous Leukemia Cells, and Acute Myelogenous Cells," The Journal of Biological Chemistry, 1986, pp. 12796-12806, Vol. 261, No. 27.	
		HOJA-LUKOWICZ, D. et al., "High-Mannose-Type Oligosaccharides from Human Placental Arylsulfatase A are Core Fucosylated as Confirmed by MALDI MS," Glycobiology, 2000, pp. 551-557, Vol. 10, No. 6.	
		International Preliminary Examination Report, PCT/AU03/01063, December 2, 2004, 7 pages.	
		International Search Report, PCT/AU03/01063, November 12, 2003, 4 pages.	
		ITO, A. et al., "A Novel Ganglioside Isolated from Renal Cell Carcinoma," The Journal of Biological Chemistry, 2001, pp. 16695-16703, Vol. 276, No. 20.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

23681/10204/DOCS/1631095.1

**Complete if Known**

<b>Application No.</b>	10/528,745
<b>Filing Date</b>	March 22, 2005
<b>First Named Inventor</b>	Nicolle Hannah Packer
<b>Art Unit</b>	Not Yet Known
<b>Examiner Name</b>	Not Yet Known
<b>Attorney Docket Number</b>	23681-10204US (Client Ref 122502)

Sheet	2	of	2
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[illegible]

Examiner  
Signature

Date  
Considered

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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

23681/10204/DOCS/1631095.1